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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,038	12/20/2001	Stephen Quirk	1443.026US1	2238

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,038

Applicant(s)

QUIRK, STEPHEN

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 29-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Claims 1-41 are pending.

Response to restriction requirement filed 09/29/2003 is acknowledged. Applicant elected, with traverse, Group III, claims 14-28, and SEQ ID No. 11. Insofar as applicants have not specifically pointed out the reasons supporting the statement of the traversal for Groups IV, applicants' election is taken to be without traverse. The restriction requirements still deemed proper and is therefore made FINAL. Claims 1-13, 29-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1-13, 29-41 is requested.

In regard to election of a particular peptide, applicant's arguments showing that the claimed peptides are all related derivatives of peptide SEQ ID No. 1 are deemed convincing. The restriction requirement is replaced with election of species requirement (species are peptides SEQ ID Nos 2-6, 8-11,14). As applicant elected SEQ ID No. 11, this peptide will be addressed for initial examination on merits; if conjugates comprising said peptide are found allowable, Examiner will extend examination to other species.

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Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 03/09/2003 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16,23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite that the backbone contains polyproline helix, loop region, etc. However, the base claim clearly distinguishes between peptide backbone, which is one of the identified SEQ ID Nos, and an "interactive domain" (which might be meant in claim 16). Thus, it is not clear how peptide backbone which has a defined sequence includes any other inserts in it. Same for claim 23.

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4. Claims 17,18,25,26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "more stable" is indefinite because it is a relative term, but no standard of reference has been provided with which to determine whether a particular product is "more stable" or not. In regard to claims 17,25, peptide SEQ IDS No. 1 is known to be exceptionally stable as it is (see, e.g., Bjornholm, 1993, first paragraph), so the meaning of "more stable" is not clear. In regard to claims 18,26, again, the meaning of "more stable" is not clear, especially in view of the broad diversity of potential "interactive domains" (see, e.g., claim 19 - how an enzymatic active site brings stability to a peptide?).

Claim Rejections - 35 U.S.C. § 101

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

5. Claims 14-28 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a conjugate of a peptide having at least 90% identity to SEQ ID No. 11 and an interactive domain (e.g., see claim 14). The latter

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may be a variety of moieties, ranging from a linker to an inhibitor domain, to a solid support (see claim 19, for example).

Credible Utility

Following the requirements of the Utility Guidelines (see: Federal Register, December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility), the first inquiry is whether a credible utility is cited in the specification for use of the conjugate. Specification hints at some "diagnostic applications" (p. 45, line 2) but does not specify them. Thus, such utility is not credible.

The next issue is whether there are any well established utilities for the conjugates of SEQ ID No. 11. No well established utilities for conjugates with this specific peptide backbone are identified in either the specification or in the cited prior art.

Substantial utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Specification describes SEQ ID No. 11 as a derivative of SEQ ID No. 1. However, even the SEQ ID No. 1 itself is known for its stability, rather than for its potential utility. As to SEQ ID No. 11, it is not possible to predict the effect of replacing a single amino acid residue in a peptide's structure or bioactivity. The amino acid sequence of the peptide is of great importance in determining the secondary and tertiary structures of the peptide. This is because the

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peptide's structure is determined by the interplay of the hydrophobic/hydrophilic, stearic and electrostatic forces among the linked amino acid residues. Therefore, changing a single residue alters these forces unpredictably, and impose a new unpredictable structure of the modified peptide. Therefore, if replacing one or more residues in a peptide unpredictably alters its structure, this replacement also may alter bioactivity unpredictably. Specification does not demonstrate any substantial utility for SEQ ID No. 11 much less for its conjugates, especially those that may further alter its structure/function unpredictably (e.g., by inserting "interactive domain" in unidentified positions of SEQ ID 11, attaching SEQ ID 11 to a solid support, etc. As noted in the utility guidelines, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Specific Utility

In the current case, there is no specific utility for SEQ ID NO: 11 or conjugates comprising thereof. The claims are drawn to a conjugate with any interactive domain without a specified function of the conjugate.

Claim Rejections - 35 U.S.C. § 112-1

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-28 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. Furthermore, as the claims are drawn not to conjugates of SEQ ID No. 11 itself, but rather to conjugates of a peptide having 90% or more similarity with SEQ ID No. 11, it is even less clear how to use the claimed invention because the specification does not specify core structure needed for homologs of SEQ ID No. 11 to carry out an (unspecified) utility. Even further, with the lack of guidance of the core structure required for any alleged utility, it is not clear how to use conjugates of SEQ ID 11 wherein the sequence of the "peptide backbone" is interrupted by insertion of an "interactive domain" - note, that specification teaches that as diverse domains as binding domains, linkers, solid support, enzymatic active sites, etc, can be inserted into the peptide's backbone (see p. 23, last full paragraph).

Conclusion.

8. No claims are allowed

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 26, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

